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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,753	01/23/2002	Sergei Bavykin	0003/00377	9563

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EXAMINER	
KIM, YOUNG J	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,753	BAVYKIN ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action responds the Amendment received on February 9, 2004.

Priority

The amendment to the specification to clarify the benefit claimed under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 112

The rejection of claims 3, 10, 12, and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on November 3, 2003 is withdrawn in view of the Amendment received on February 9, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13 and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Bavykin et al. (US 2003/0096229 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Bavykin et al. disclose a method of labeling DNA or RNA (thus nucleic acids) comprising: i) reacting the nucleic acids with hydrogen peroxide and 1,10-phenanthroline and $CuSO_4$ (or redoxactive coordination complex), producing free-aldehyde moieties on the nucleic acids; ii) reacting the free-aldehyde moieties on the nucleic acids with ethylenediamine; and iii) labeling the product [0060]-[0079], thereby anticipating instant claims 1-13 and 16-18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over Bavykin et al. (US 2003/0096229 A1) in view of Sheldon et al. (US Patent No. 4,617,261, issued October 14, 1986).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of

invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of Bavykin et al. is already set forth above.

Bavykin et al., while employing elevated temperature to denature double stranded nucleic acids, do not employ denaturing agents (or double-strand weakening agent of claim 14), wherein said denaturing agents are urea, carbonic acid, ethyl carbonate, cyanamide, or urethane (instant claim 15).

Sheldon et al. disclose a method of labeling a nucleic acid wherein a double stranded nucleic acid is denatured via well known denaturant such as urea, alcohols, amides, phenols, sulfoxides, thiocyanate, perchlorate, and elevated temperatures (column 18, lines 18-36).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to incorporate a well-known denaturant agent of Sheldon et al. into the teachings of Bavykin et al. in order to denature double stranded nucleic acids prior to their labeling for the following reasons.

As already demonstrated by Sheldon et al., various denaturing agents are employed to render single stranded, double-stranded nucleic acids prior to their labeling. Sheldon et al., among the lists of denaturation techniques, list elevated temperature as well as the use of other reagents (*i.e.* – urea). The instant specification, on section [0027], also acquiesces that operating the protocols at temperatures approaching the boiling point of water, or in the presence of a denaturing agent (such as urea formamide, or guanidine chloride), confers unfolding of the nucleic acids.

As such knowledge was well known in the art of nucleic acid labeling, one of ordinary skill in the art would have had a reasonable expectation of success at modifying the teachings of Bavykin et al. to employ a denaturant such as urea to render double stranded nucleic acids to single nucleic acids prior to their labeling.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 16-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 09/751,654. Although the conflicting claims are not identical, they are not patentably distinct from each other because the labeling method of the instant application and the labeling method of the '654 application involves the use of fragmentation-labeling via use of readox complex and hydrogen peroxide to produce a free-aldehyde moieties on the nucleic acid to be labeled. The difference between the instantly claimed method and that of the '654 application is in that the method of the '654 application involves the use of column, wherein the fragmentation and labeling is achieved in a column. However, the labeling method of the instant application is disclosed by that of the '654 application, rendering the instant claims obvious over claims of the '654 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants are advised that the '654 application has been recently allowed by another examiner. Therefore, without a proper terminal disclaimer, the instant provisional rejection would be maintained after the patent is issued on said '654 application.

Claims 14 and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 09/751,654 in view of Sheldon et al. (US Patent No. 4,617,261, issued October 14, 1986).

The teachings of '654 application has been already discussed above.

The claimed method of the '654 application, while employing elevated temperature to denature double stranded nucleic acids, do not employ denaturing agents (or double-strand weakening agent of claim 14), wherein said denaturing agents are urea, carbonic acid, ethyl carbonate, cyanamide, urethane (instant claim 15).

Sheldon et al. disclose a method of labeling a nucleic acid wherein a double stranded nucleic acid is denatured via well known denaturant such as urea, alcohols, amides, phenols, sulfoxides, thiocyanate, perchlorate, and elevated temperatures (column 18, lines 18-36).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to incorporate a well-known denaturant agent of Sheldon et al. into the claimed method of the '654 application in order to denature double stranded nucleic acids prior to their labeling for the following reasons.

As already demonstrated by Sheldon et al., various denaturing agents are employed to render single stranded, double-stranded nucleic acids prior to their labeling. Sheldon et al., among the lists of denaturation techniques, list elevated temperature as well as the use of other reagents (*i.e.* – urea). The instant specification, on section [0027], also acquiesces that operating the protocols at temperatures approaching the boiling point of water, or in the presence of a denaturing agent (such as urea formamide, or guanidine chloride), confers unfolding of the nucleic acids.

As such knowledge was well known in the art of nucleic acid labeling, one of ordinary skill in the art would have had a reasonable expectation of success at modifying the method of

the '654 application to employ a denaturant such as urea to render double stranded nucleic acids to single nucleic acids prior to their labeling.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

This is a provisional obviousness-type double patenting rejection.

Applicants are advised that the '654 application has been recently allowed by another examiner. Therefore, without a proper terminal disclaimer, the instant provisional rejection would be maintained after the patent is issued on said '654 application.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (517) 273-0785. Any inquiry of a

general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0507.

Young J. Kim
Patent Examiner
Art Unit 1637
7/9/04

yjk